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10/588,691	08/08/2006	Matthew Earl Meyer	3380.EGMD.NP	9672
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EXAMINER				
WOO, JULLAN W				
ART UNIT		PAPER NUMBER		
3773				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/588,691

**Applicant(s)**

MEYER, MATTHEW EARL

**Examiner**

Julian W. Woo

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/CD)  
Paper No(s)/Mail Date 9/28/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 29 is objected to because of an informality, which can be corrected as follows: In line 2, "sheilding" should be replaced by --shielding--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-28, 35, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claim 1, it is not certain how the sheath is "activatable." That is, what characterizes sheath activation? With respect to base claim 35, "the needle body" lacks antecedent basis.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 14-17, and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomas et al. (5,549,629). Thomas et al. disclose, in figures 2 and

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4 and in col. 1, line 7-33 and col. 2, lines 11-26, a suture needle assembly or suturing apparatus, the suture needle assembly or suturing apparatus including a suture needle (8), an activatable sheath (7) or hood-shaped shield, a needle holder (13), and suture material (4); where the sheath is reversibly activatable (i.e., movable) in initially armed or disarmed configurations, where the needle comprises an aperture (9) or groove, where the sheath is substantially flush along a needle outer surface in a retracted position.

6. Claims 1-3, 18, 19, 30, 31, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Imran (5,236,424). Imran discloses, at least in figures 2 and 4 an dol. 2, line 29 to col. 3, line 39, a suture needle assembly including a suture needle (31, connected to suture material 63), and an activatable sheath (59) activatable by electricity or heat (when elements 56 and 57 are powered), where the sheath comprises a cylindrical projection or loop (59). Imran also discloses a modified needle holder including a needle holder (combination of elements 56 and 57) having first and second holding tips (proximal end of 56 and distal end of 57, respectively), each connected to a power source (via 61 or 63), and a control switch (12) or means for circuit regulation.

7. Claims 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. (5,382,257). Lewis et al. disclose, at least in figures 1A and 3-3B, a suture needle including a needle body (e.g., 23), a flexible extension member (e.g., 21), and a needle distal tip (e.g., 25), the tip being attached to the needle body by the flexible extension member, which is

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configured to selectively allow the distal tip to pivot with respect to the needle body.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. (5,549,629) in view of Yoon (5,810,851). Thomas et al. disclose the invention substantially as claimed. Thomas et al. disclose, at least in the figures and col. 2, lines 11-44; providing a safety suture needle, shielding a portion of the needle with cover 14, and performing a suturing procedure, but do not disclose that the needle has a shape memory alloy for shielding. Yoon teaches, at least in col. 6, lines 22-37; a suturing needle (26) formed of shape memory alloy (e.g., nitinol). It would have been obvious to one having ordinary

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skill in the art at the time the invention was made, in view of Yoon, to form the cover of Thomas et al. out of a shape memory material. Such a material is strong, flexible, and medically-acceptable. Moreover, it has been held to be within the general skill of a worker in the art to select a known material, such as a shape memory material, on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125, USPQ 416.

10. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (5,382,257) in view of Cole et al. (6,068,648). Lewis et al. disclose the invention substantially as claimed. Lewis et al. disclose a suture needle including a unifying element (e.g., 21 or 40) continuously connected to a needle casing (e.g. combination of 23 and 25 or 36 and 38), whereupon a fracturing event of the needle casing, a needle part (e.g., 25 or 38) is prevented from dissociation from another needle part (e.g., 23 or 36). However, Lewis et al. do not disclose that the unifying element comprises a shape memory material or nitinol. Cole et al. teach, in col. 5, lines 7-13; a unifying element (20) comprising a shape memory material or nitinol. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Cole et al., to form the unifying element of Lewis et al. out of a shape memory material or nitinol. Such a material is strong, flexible, and biocompatible. Moreover, it has been held to be within the general skill of a worker in the art to select a known material, such as nitinol, on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125, USPQ 416.

***Allowable Subject Matter***

11. Claims 4-13 and 24-28 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a suture needle assembly including, inter alia, a suture needle, an activatable sheath, where the needle comprises an external casing and a sheath activator that is electrically or thermally responsive to the casing.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773